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(54) **Coaxial bipolar connector assembly for implantable medical device.**

(57) A connector assembly for an implantable medical device includes a receptacle (10) for receiving the proximal end (12) of a coaxial bipolar lead (14) having a distal end attachable to a desired tissue location. The receptacle (10) includes an open end (18) for receiving the proximal end (12) of the lead (14) and a closed end (21) carrying a conductive pin (22). The pin (22) has a portion inside the receptacle projecting towards the open end (18) and adapted to make electrical contact with one of the lead conductor terminals (46). The proximal end (12) of the lead (14) has a conductive socket for receiving the projecting portion of the pin (22) inside the receptacle (10). An adapter terminal (84) may be used to convert the proximal end (12) of the lead (14) to the industry VS-1 standard.

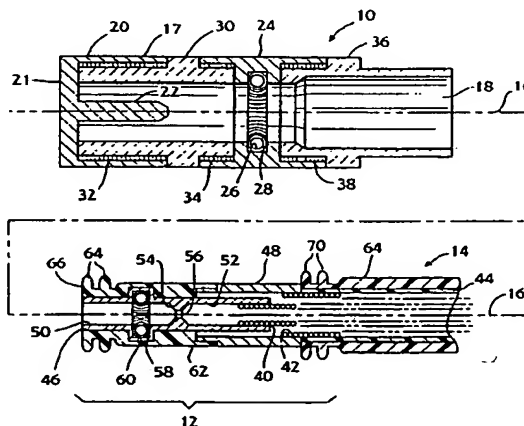


Fig. 1

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The present invention relates generally to implantable medical devices such as cardiac pacemakers and particularly to a connector assembly for such devices including a receptacle and a lead for providing a reliable electrical connection between a desired tissue location and the electronic circuits of the implantable medical device.

Although it will become evident to those skilled in the art that the present invention is applicable to a variety of implantable medical devices utilising pulse generators to stimulate selected body tissue, the invention and its background will be described in terms of a specific example of such devices, namely, cardiac pacemakers for providing precisely controlled stimulation pulses to the heart.

Present day cardiac pacemakers are typically designed to be implanted in a "pocket" of fatty tissue near the patient's upper breast or lower abdomen. Accordingly, the electronic circuits within the pacemaker are hermetically sealed within a housing made of a material compatible with body tissue. Electrical connection is made with the pacemaker electronic circuits via feedthrough terminals that pass through the hermetically sealed housing. The feedthrough terminals are electrically connected to a connector receptacle in the pacemaker housing for receiving the proximal end of a pacing lead. The lead has a distal end having electrodes attached to the desired tissue location. For cardiac pacing, such a lead is typically inserted through one of the main veins of the patient, for example, the superior vena cava so that the distal end of the lead is directed inside the heart.

Good electrical contact must be maintained between the proximal end of the pacing lead and the pacing lead receptacle on the pacemaker. Further, the connection must be secure so that it does not come apart during use yet it must be detachable in the event the pacemaker or lead needs to be replaced. Moreover, the connection must at all times remain insulated and sealed from body fluids; such fluids are conductive and could cause an electrical short circuit if permitted to infiltrate the connector assembly.

Multiconductor pacing leads such as coaxial bipolar leads include a pin electrode projecting from the proximal tip or extremity of the lead and one or more proximal ring electrodes. The pin and ring electrodes are designed to make secure electrical contact with mating terminals carried by the pacemaker lead receptacle. Recently, there has been an effort to standardise this interface between the pacing lead and pacemaker. See, for example, Calfee et al., "A Voluntary Standard For 3.2mm Unipolar and Bipolar Pacemaker Leads and Connectors," PACE, Vol. 9, pp. 1181-85 (November-December 1986). The standard described therein, now referred to by the designation VS-1 (Voluntary Standard - 1), has been adopted by most pacemaker manufacturers worldwide. Among other things, the VS-1 standard offers and specifies

the dimensions of the pacing lead and the pacemaker receptacle into which the proximal end of the pacing lead is inserted. Examples of VS-1 connectors are shown in US Patent Nos. 5,076,270; 5,012,807; 4,848,346; and 4,934,366.

The very nature of an implantable device makes it desirable, of course, to reduce as much as possible the size of the housing of such a device. The VS-1 standard connector receptacle/pacing lead dimensions are factors which contribute to determining the size of the housing of the implantable medical device. It has now become evident that these standard dimensions place constraints on the ability to reduce the size of the housing. Accordingly, it would be desirable to have a connector assembly that removes the constraints imposed by the VS-1 standard connector assembly dimensions so as to permit the design of more compact implantable medical devices. At the same time, it would also be desirable for the pacing lead comprising part of such an assembly to be adaptable for use with pacemakers having pacing lead receptacles complying with the VS-1 standard.

According to one aspect of the invention, there is provided a receptacle arranged to form part of a connector assembly for an implantable medical device having electronic circuits, the receptacle being adapted to receive the proximal end of a bipolar lead having a pair of coaxial conductors and associated terminals, thereby connecting the conductors of the lead to the circuits of the implantable medical device, the receptacle comprising: a side wall, an open end for receiving the proximal end of the lead, and a closed end; a first terminal at the closed end for connecting the first lead terminal to the circuits of the implantable medical device; and a second terminal in the side wall for connecting the second lead terminal to the circuits of the implantable medical device; characterised in that the first receptacle terminal comprises an electrically conductive pin carried by the closed end, a portion of which is disposed within the receptacle and projects towards the open end, the pin including an end opposite the inside portion for connection to the circuits of the implantable medical device, while the projecting portion of the pin is arranged to make electrical contact with the first lead terminal.

In accordance with the present invention therefore, there is provided for use in an implantable medical device connector assembly a novel receptacle adapted to receive the proximal end of a coaxial, bipolar lead. The receptacle is adapted to connect the conductor terminals of the lead to the electronic circuits of the implantable medical device. The receptacle comprises a side wall, an open end for receiving the proximal end of the lead, and a closed end. The closed end of the receptacle carries an electrically conductive pin, a portion of which is disposed inside the receptacle and projects toward the open end thereof and which is adapted to make electrical con-

tact with one of the lead conductor terminals. The end of the pin opposite the interior portion thereof is adapted for connection to the electronic circuits of the implantable medical device. The receptacle includes in the side wall thereof a terminal for coupling the other of the lead conductor terminals to the electronic circuits of the implantable medical device.

Preferably, the receptacle comprises an elongate tubular structure having a central longitudinal axis, the electrically conductive pin being centred on and extending along the longitudinal axis. Preferably, the second receptacle terminal comprises a conductive ring in the side wall, including yieldable contact means adapted to engage the second lead terminal. Preferably, the closed end of the receptacle comprises an electrically conductive end wall, the pin being integral with the end wall. There is preferably an insulating tubular section interposed between the conductive ring and the conductive end wall.

According to a second aspect of the invention, there is provided a bipolar lead for providing an electrically conductive path between an implantable medical device and a desired tissue location, the lead being adapted to be received by a receptacle on the implantable medical device, the lead including: a inner conductor and an outer conductor insulated from each other; a distal end for connection to the desired tissue location; a proximal end for connection to the electronic circuits of the implantable medical device; a first terminal at the proximal end of the lead connected to the inner conductor of the lead and arranged to engage a first electrical contact element connected to the circuits of the implantable medical device; a second terminal mounted at the proximal end of the lead having an outer surface adapted to engage a second electrical contact element connected to the circuits of the implantable medical device and an inner surface coupled to the outer conductor of the lead; and means (64,70) at the proximal end of the lead for sealingly engaging the receptacles; characterised in that the first lead terminal comprises a conductive socket mounted at the proximal end of the lead, the socket having a first portion connected to the inner conductor of the lead and a second portion proximate the tip of the lead and adapted to receive the said first electrical contact element.

Pursuant to this aspect of the invention, therefore there is provided a coaxial, bipolar lead having a novel proximal end which is adapted to mate with the aforescribed receptacle. A conductive socket at the proximal end of the lead has a first portion connected to the inner conductor of the coaxial lead and a second portion proximate the tip of the lead adapted to receive the inwardly projecting portion of the conductive pin in the receptacle. By eliminating the pin projecting from the tip of a standard VS-1 connector along with the associated pin-receiving block on the connector cavity of the standard connector assembly,

the overall length of the connector assembly is substantially reduced thereby making possible the design of more compact implantable medical device.

Preferably, the second portion of the socket includes yieldable electrical contact means adapted to provide a reliable electrical connection between the socket and the first electrical contact elements. Preferably, the sealingly engaging means includes a first elastomeric ring seal about the second portion of the socket and a second elastomeric ring seal, the second lead terminal being located between the first and second ring seals.

The lead of the invention may be made to be compatible with an existing VS-1 connector assembly by means of an adapter terminal having at one end a projecting tip electrode conforming to VS-1 standard dimensions and at the other end a pin adapted to be received by the conductive socket at the proximal end of the lead.

The invention also extends to the receptacle and lead in combination. Thus, the invention may provide a connector assembly for an implantable medical device having electronic circuits, said connector assembly including: (1) a receptacle comprising: (a) a side wall having an electrically conductive terminal for connection to the circuits of the implantable medical device; (b) an open end; (c) a closed end; and (d) an electrically conductive pin carried by said closed end, the pin having an inner portion disposed inside said receptacle and projecting toward the open end thereof, the pin including an end opposite the inner portion thereof for connection to the circuits of said implantable medical device; and (2) a bipolar lead for providing an electrically conductive path between the implantable medical device and a desired tissue location, the lead including: (a) a distal end for connection to the desired tissue location; (b) a proximal end adapted to be received by the open end of the receptacle; (c) a tip; (d) a pair of coaxial conductors including an inner conductor and an outer conductor, said conductors being insulated from each other; (e) a conductive socket mounted at the proximal end of said lead, said socket having a first portion connected to the inner conductor of the lead and a second portion proximate the tip of said lead for receiving the inner portion of the receptacle pin; (f) a conductive terminal mounted on the proximal end of said lead, said terminal having an outer surface for engaging the terminal on the side wall of the receptacle and an inner surface coupled to the outer conductor of said lead; and (g) means mounted about the proximal end of the lead sealingly engaging the side wall of the receptacle.

The invention may be carried into practice in various ways and an embodiment will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 is a longitudinal cross-section of a pace-

maker connector assembly including a receptacle and the corresponding proximal end of a coaxial, bipolar lead, in accordance with the invention; Figure 2 is a side elevation, partly in section, comparing the length of the connector assembly according to the present invention with that of a typical connector assembly of the prior art complying with the VS-1 standard; and

Figure 3 is a side elevation, partly in cross-section, of the proximal end of a pacing lead in accordance with the present invention shown in combination with a tip electrode adapter for converting the pacing lead to conform to the VS-1 standard.

Referring to Figure 1, there is shown a connector assembly including a connector cavity or receptacle 10 forming part of a cardiac pacemaker and the proximal end 12 of a pacing lead 14 adapted to be releasably received by the receptacle 10 for coupling the electronic pulse circuits of the pacemaker to the heart to be stimulated thereby.

The receptacle 10 is basically a tubular structure symmetrical about a longitudinal central axis 16 and having a cylindrical side wall 17. The receptacle has an open end 18 and an opposite end closed by a cup shaped conductive terminal 20 having an end wall 21. The terminal 20 includes a conductive pin 22 extending inwardly along the central axis 16 toward the open end 18 of the receptacle. The terminal 20 comprises one of a pair of receptacle terminals adapted to be coupled to the electronic circuits of the cardiac pacemaker. The other terminal, identified by the reference numeral 24, is in the form of a ring having a generally T-shaped cross-sectional configuration as best seen in the upper portion of Figure 1. The inner surface of the central portion of the receptacle ring terminal 24 has an annular groove 26 within which is retained a conductive garter spring contact 28. Interposed between the terminals 20 and 24 and isolating them electrically is a ceramic insulator tube 30 hermetically bonded to the terminals 20 and 24 by glass seals 32 and 34, respectively. A second ceramic insulator tube 36, defining the open end 18 and also hermetically bonded to the ring electrode 24 by a glass seal 38, extends to the right from the ring terminal 24 as seen in Figure 1 and completes the structure of the receptacle 10. Although ceramic material is preferred for the insulating tubes 30 and 36, any suitable nonconductive material, such as epoxy or polymer substance, could be used to perform this insulating function provided suitable hermetic bonds are made between the insulators and the terminals 20 and 24. In applications where hermeticity is not required, that is, when the connector elements are cast into an epoxy connector top outside of the hermetic electronics enclosure such as shown in US Patent No. 5,012,807, the insulative function may be performed by plastics materials that do not require hermetic bonding.

The pacing lead 14 is a two conductor lead commonly known in the art as a coaxial bipolar lead. Thus, the lead 14 includes an inner helically wound conductor 40 surrounded by an outer helically wound conductor 42. As is known, these conductors (only portions of which are shown in Figure 1) are separated by an insulating layer (not shown) and the outer conductor is covered by an insulating sleeve a portion 44 of which is shown in the lower part of Figure 1. The proximal lead end 12 includes an inner lead conductor terminal in the form of a conductive, longitudinally extending, tubular pin socket 46 of stainless steel or the like disposed along the central axis 16. The proximal lead end 12 also has an outer lead conductor terminal in the form of a conductive ring 48 also of stainless steel or similar material. The pin socket 46 has two sections: an outer section 50 adapted to receive the pin 22 and an inner section 52 for receiving the inner lead conductor 40. The socket sections 50 and 52 are separated by a transverse wall 54 having a central aperture 56 through which a stylet guide wire may be temporarily inserted during the implantation procedure. The wall of the pin receiving section 50 includes an annular recess 58 retaining a garter spring contact 60 which assures a secure, low resistance connection between the pin 22 and the socket 46 when the proximal end 12 of the pacing lead is in place within the receptacle 10. A like, secure connection is provided by the garter spring contact 28 between the ring terminals 24 and 48.

Surrounding an outer portion of the socket 46 is a first elastomeric sealing sleeve 62 having a set of sealing rings 64 adjacent the tip 66 of the pacing lead. Similarly, a second elastomeric sealing sleeve 64 having a set of sealing rings 70 is disposed adjacent the ring terminal 48 to the right thereof as seen in Figure 1. As is well known, the sealing rings 65 and 70 cooperate with the interior wall of the receptacle when the proximal end 12 of the pacing lead is inserted into the receptacle 10 to prevent body fluids from penetrating the receptacle and possibly causing an electrical malfunction. The sleeves 62 and 68 may be made of any resilient, mouldable material such as silicone compatible with body tissue.

Figure 2 shows the receptacle 10 of the present invention incorporated into a cardiac pacemaker having a housing 80, electronic circuits 82 and a power supply in the form of a battery 84. Conductors 86 and 88 connect the electronic circuits 82 to the receptacle pin terminal 20 and ring terminal 24, respectively. Figure 2 also compares the envelope of the housing 80 with that of a housing 80' of a pacemaker utilizing a standard VS-1 connector system. Such a standard system, shown in phantom in Figure 2 for comparison purposes, includes a pin 90 projecting from the tip of the pacing lead along with a mating socket 92 for receiving the pin. It will thus be seen that the receptacle 10 of the present invention is substantially shorter

than that of the VS-1 system making possible a substantial reduction in the overall width of the pacemaker housing.

The pacing lead 14 of the present invention can be adapted to be compatible with an existing VS-1 pacemaker connector assembly. In this regard, Figure 3 shows an adapter terminal 94 having a projecting tip electrode 96 conforming to VS-1 standard dimensions and a pin 98 received by the pin socket 50 in the end of the pacing lead. For good electrical contact, the pin 98 may be provided with an annular groove 100 for mating with the garter spring contact 60. The adapter terminal 94 may also include an axially extending passageway 102 through which a stylet guide wire may be temporarily inserted.

Claims

1. A receptacle (10) arranged to form part of a connector assembly for an implantable medical device having electronic circuits (82), the receptacle being adapted to receive the proximal end (12) of a bipolar lead (14) having a pair of coaxial conductors (40,42) and associated terminals (48,50), thereby connecting the conductors (40,42) of the lead (14) to the circuits (82) of the implantable medical device, the receptacle (10) comprising: a side wall (17), an open end (18) for receiving the proximal end (12) of the lead (14), and a closed end (21); a first terminal (20) at the closed end for connecting the first lead terminal (46) to the circuits (82) of the implantable medical device; and a second terminal (24) in the side wall (17) for connecting the second lead terminal (48) to the circuits (82) of the implantable medical device; characterised in that the first receptacle terminal (20) comprises an electrically conductive pin (22) carried by the closed end (21), a portion of which is disposed within the receptacle (10) and projects towards the open end (18), the pin (22) including an end opposite the inside portion for connection to the circuits (82) of the implantable medical device, while the projecting portion (22) of the pin is arranged to make electrical contact with the first lead terminal (46).
2. A receptacle as claimed in Claim 1, characterised in that the receptacle comprises an elongate tubular structure having a central longitudinal axis (16), the electrically conductive pin (22) being centred on and extending along the longitudinal axis (16).
3. A receptacle as claimed in Claim 1 or Claim 2, characterised in that the second receptacle terminal (24) comprises a conductive ring in the side wall, including yieldable contact means (28)

adapted to engage the second lead terminal (48).

4. A receptacle as claimed in Claim 3, characterised in that the yieldable contact means (28) comprises a coil garter spring contact.
5. A receptacle as claimed in any preceding Claim, characterised in that the closed end (21) of the receptacle comprises an electrically conductive end wall, the pin (22) being integral with the end wall.
6. A receptacle as claimed in Claim 5, characterised in that the receptacle includes an insulating tubular section (30) interposed between the conductive ring (24) and the conductive end wall (21).
7. A bipolar lead (14) for providing an electrically conductive path between an implantable medical device and a desired tissue location, the lead (14) being adapted to be received by a receptacle (10) on the implantable medical device, the lead (14) including: a inner conductor (40) and an outer conductor (42) insulated from each other; a distal end for connection to the desired tissue location; a proximal end (12) for connection to the electronic circuits (82) of the implantable medical device; a first terminal (46) at the proximal end (12) of the lead (14) connected to the inner conductor (40) of the lead and arranged to engage a first electrical contact element (22) connected to the circuits (82) of the implantable medical device; a second terminal (48) mounted at the proximal end (12) of the lead having an outer surface adapted to engage a second electrical contact element (28) connected to the circuits (82) of the implantable medical device and an inner surface coupled to the outer conductor (42) of the lead; and means (64,70) at the proximal end (12) of the lead for sealingly engaging the receptacles (10); characterised in that the first lead terminal (46) comprises a conductive socket mounted at the proximal end (12) of the lead, the socket having a first portion (52) connected to the inner conductor (40) of the lead and a second portion (50) proximate the tip of the lead and adapted to receive the said first electrical contact element (22).
8. A lead as claimed in Claim 7, characterised in that the second portion (50) of the socket includes yieldable electrical contact means (60) adapted to provide a reliable electrical connection between the socket and the first electrical contact elements (22).
9. A lead as claimed in Claim 8, characterised in that the yieldable contact means (60) comprises a coil garter spring contact.

10. A lead as claimed in any of Claims 8 to 9, characterised in that the sealingly engaging means includes a first elastomeric ring seal (64) about the second portion of the socket and a second elastomeric ring seal (70), the second lead terminal (48) being located between the first and second ring seals (64,70). 5
11. A lead as claimed in any of Claims 7 to 10, characterised by an adapter terminal (94) removably located in the second portion (50) of the socket for connecting the lead (14) to a standard VS-1 connector receptacle on an implantable medical device. 10 15
12. A connector assembly for an implantable medical device having electronic circuits, characterised in that it comprises a receptacle (10) as claimed in any of Claims 1 to 6 on the device in combination with a lead (14) as claimed in any of Claims 7 to 11. 20

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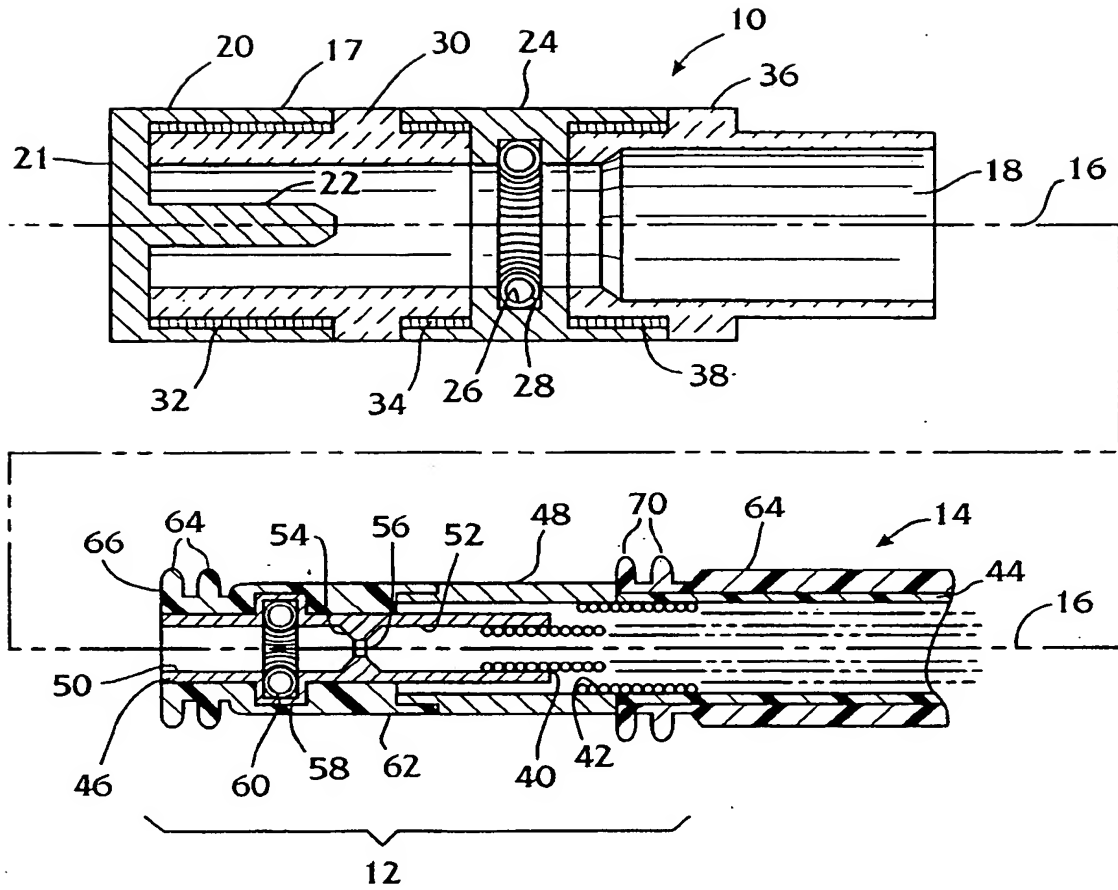


Fig. 1

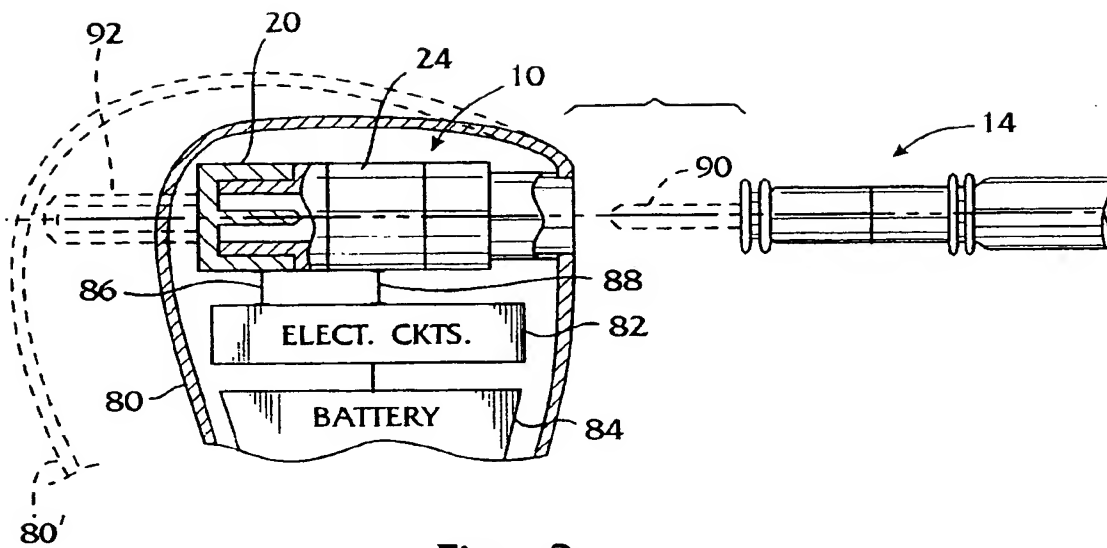


Fig. 2

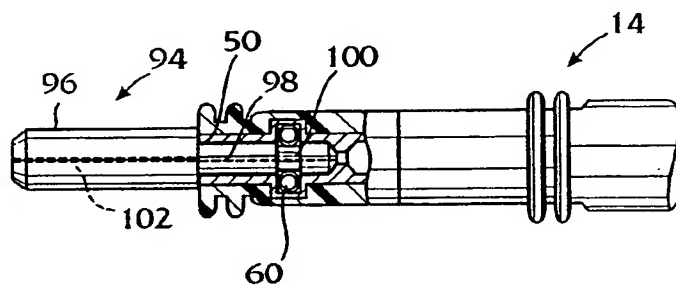


Fig. 3



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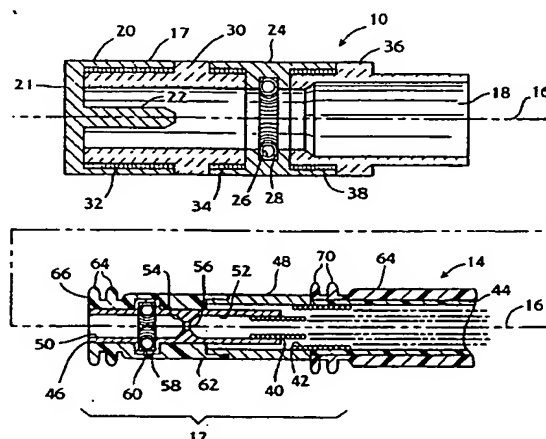


Fig. 1

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European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 93 30 6968

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
X	US-A-4 387 727 (SANDSTROM)	1-3,5,7, 11	A61N1/375 A61N1/05
A	* column 2, line 48 - column 3, line 51 *	4,6, 8-10,12	
A	US-A-4 951 687 (UFFORD) * column 3, line 39 - line 63 *	1,7	
A	EP-A-0 339 877 (MEDTRONIC) * claim 1 *	1,7	
A	EP-A-0 448 760 (SIEMENS) * abstract *	1,7	
			TECHNICAL FIELDS SEARCHED (Int.Cl.5)
			A61N.
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 28 October 1994	Examiner Taccoen, J-F
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